Proposed Registration Decision PRD2013-06

Garlic Powder

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Table of Contents

Overview 1
Proposed Registration Decision for Garlic Powder 1
What Does Health Canada Consider When Making a Registration Decision? 1
What Is Garlic Powder? 2
Health Considerations 2
Environmental Considerations 3
Value Considerations 4
Measures to Minimize Risk 4
Next Steps 4
Other Information 5
Science Evaluation 7
Garlic Powder 7
1.0 The Active Ingredient, Its Properties and Uses 7
1.1 Identity of the Active Ingredient 7
1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product 7
1.3 Directions for Use 8
1.4 Mode of Action 8
2.0 Methods of Analysis 9
2.1 Methods for Analysis of the Active Ingredient 9
2.2 Method for Formulation Analysis 9
2.3 Methods for Residue Analysis 9
3.0 Impact on Human and Animal Health 9
3.1 Toxicology Summary 9
3.2 Food Residue Exposure Assessment 9
3.3 Occupational/Bystander Exposure and Risk Assessment 9
4.0 Impact on the Environment 10
4.1 Fate and Behaviour in the Environment 10
4.2 Environmental Risk Characterization 10
5.0 Value 10
5.1 Effectiveness Against Pests 10
5.1.1 Acceptable Efficacy Claims 10
5.2 Economics 11
5.3 Sustainability 11
5.3.1 Survey of Alternatives 11
5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management 11
5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance 11
5.3.4 Contribution to Risk Reduction and Sustainability 11
6.0 Pest Control Product Policy Considerations 12
6.1 Toxic Substances Management Policy Considerations 12
6.2 Formulants and Contaminants of Health or Environmental Concern 12

7.0 Summary 13
7.1 Human Health and Safety 13
7.2 Environmental Risk 13
7.3 Value 13
8.0 Proposed Regulatory Decision 14
List of Abbreviations 15
Appendix I Tables and Figures 17
Table 1 Summary of Fungicide Alternatives for the Uses Supported with Influence WP 17
Table 2 Use (Label) Claims Proposed by Applicant and Whether Acceptable or Unsupported 17
References 19

Overview

Proposed Registration Decision for Garlic Powder

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Garlic Powder Technical and Influence WP, containing the technical grade active ingredient garlic powder, to suppress seed rot, pre-emergence damping-off and root rot on greenhouse peppers and greenhouse ornamentals.

Garlic Powder Technical (Registration Number 29666) is fully registered in Canada to suppress powdery mildew on greenhouse food crops (cucumbers and tomatoes) and grape, as well as scab on apple, crabapple and pear. The detailed review for garlic powder can be found in Proposed Regulatory Decisions PRD2010-11, *Garlic Powder* and PRD2012-22, *Garlic Powder*, as well as in Registration Decisions RD2010-11, *Garlic Powder* and RD2013-02, *Garlic Powder*. Use on greenhouse ornamentals represents a major new use for the active ingredient garlic powder.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Garlic Powder Technical and Influence WP.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on garlic powder, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on garlic powder, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Garlic Powder?

Garlic powder is the active ingredient in the end-use product Influence WP, a wettable powder formulation. This fungicide is used to suppress powdery mildew and seedling diseases on certain greenhouse crops and ornamentals.

Health Considerations

Can Approved Uses of Garlic Powder Affect Human Health?

Garlic powder is unlikely to affect human health when used according to label directions.

Exposure to garlic powder may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, garlic powder, is of low acute toxicity by the oral and dermal routes and is slightly irritating to eyes and skin. Due to the irritative nature of garlic, inhalation exposure may cause throat irritation. There is potential for skin sensitization to occur when skin is repeatedly exposed to the garlic powder. Therefore, cautionary statements alerting users to this sensitization concern are required on product labels.

Inhalation and dermal exposures are likely for occupational workers and commercial applicators. Anyone entering the sprayed areas before the spray is dried may be exposed dermally. Therefore,

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.
[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

appropriate precautionary statements and a restricted entry statement are required on the Influence WP label to mitigate such exposure concerns.

Based on garlic's long history of consumption as a food and in natural health products, there is little indication of short- or long-term toxic effects from exposure to garlic powder from the use of the commercial end-use product.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use of Influence WP for greenhouse non-food crops as a fungicide to be applied to greenhouse ornamentals should not result in additional exposure to sources of food or drinking water beyond currently registered food uses. In addition, the new crop, greenhouse peppers is being added to the Influence WP label.

Garlic is used for culinary purposes world-wide and is also consumed for its medicinal values. Garlic powder is rapidly degraded in the environment, so exposure from residues in water and from treated food commodities is likely to be minimal. Therefore, these new uses of garlic powder are not expected to result in dietary risk from consuming food or drinking water.

Occupational Risks From Handling Influence WP

Occupational risks are not of concern when Influence WP is used according to label directions, which include protective measures.

Occupational exposure to individuals mixing, loading or applying Influence WP is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary and hygiene statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Garlic Powder Technical is Introduced Into the Environment?

Garlic Powder Technical is not persistent and the proposed use is not expected to pose a risk to non-target terrestrial or aquatic organisms.

Garlic Powder Technical is derived from a naturally-occurring food commodity (garlic bulb). Allyl sulfides are volatile and, as such, volatilization is expected to be an important route of dissipation for this technical active in the environment. Allyl sulfides are expected to degrade in air by reaction with hydroxyl radicals. The environmental exposure from the use of garlic powder is expected to be minimal for the proposed use in greenhouses for ornamentals and pepper.

Garlic powder is non-toxic to honey bees and birds and is slightly toxic to fish and aquatic invertebrates on an acute basis. Garlic Powder Technical poses negligible risk to non-target terrestrial or aquatic organisms from this proposed use.

Value Considerations

What Is the Value of Influence WP?

Influence WP is a non-conventional fungicide that provides suppression of seed rot, pre-emergence damping-off and root rot on greenhouse peppers and greenhouse ornamentals.

Influence WP represents an alternative mode of action to conventional fungicides and poses a low risk of resistance development.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Influence WP to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

On the label for Influence WP, the following statement should be included "Individuals who are sensitive or allergic to garlic should avoid handling the product."

Next Steps

Before making a final registration decision on garlic powder, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on garlic powder (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Garlic Powder

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Garlic powder
Function	
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	N/A
2. **Chemical Abstracts Service (CAS)**	N/A
CAS number	N/A
Molecular formula	N/A
Molecular weight	N/A
Structural formula	N/A
Purity of the active ingredient	100%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Garlic Powder

Property	Result
Colour and physical state	White-yellow powder
Odour	Slight garlic odour
Melting range	N/A (mixture of various compounds)
Boiling point or range	N/A (the product is solid)
Density	0.33–0.35 g/cm^3
Vapour pressure at 20°C	N/A
Henry's law constant at 20°C	N/A
Ultraviolet (UV)-visible spectrum	N/A
Solubility in water	40 g/L

Property	Result
Solubility in organic solvents at 20°C (g/100 mL)	N/A
n-Octanol–water partition coefficient (K_{OW})	N/A
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	N/A

End-Use Product—Influence WP

Property	Result
Colour	White-yellow
Odour	Slight garlic odour
Physical state	Powder
Formulation type	Wettable powder
Guarantee	70.1%
Container material and description	Fiber drums Plastic: High density polyethylene (HDPE), polyethylene (PE), and polypropylene (PP)
Density	0.33 g/cm^3
pH	5.2–5.8
Oxidizing or reducing action	The active ingredient, garlic powder, is a mixture of various compounds. As a result, it might contain some oxidizing agents.
Storage stability	Not required.
Corrosion characteristics	The end-use product is not expected to be corrosive.
Explodability	The end-use product is not expected to be explosive.

1.3 Directions for Use

Influence WP is to be applied once as a drench at seeding for suppression of seed rot, pre-emergence damping-off and root rot on greenhouse peppers and greenhouse ornamentals. A rate of 10–20 kg product per 300 m^2 is required to achieve good coverage of the substrate surface.

1.4 Mode of Action

Many details of the fungicidal mode of action of garlic powder remain to be determined; however, the active ingredient has been demonstrated to cause loss of turgor in target pathogen cells and a general collapse of hyphae and spores.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Based on the nature of the product, this requirement is waived.

2.2 Method for Formulation Analysis

Based on the nature of the product, this requirement is waived.

2.3 Methods for Residue Analysis

Methods for residue analysis were not required.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Proposed Regulatory Decision PRD2010-11, *Garlic Powder* for a toxicology summary of the active ingredient, garlic powder.

Garlic powder is of low acute toxicity by the oral and dermal routes and is slightly irritating to eyes and skin. Inhalation exposure to garlic powder is likely to cause irritation of the respiratory tract and may result in allergic reaction.

3.2 Food Residue Exposure Assessment

Refer to PRD2010-11, *Garlic Powder* for a Food Residue Exposure Assessment of the active ingredient, garlic powder.

There is reasonable certainty that no harmful effects will result from dietary exposure to residues of the end-use products based on the low levels of toxicity, the long history of safe consumption of garlic and the low potential for exposure. Consequently, the PMRA has not required the establishment of a maximum residue limit for garlic powder.

3.3 Occupational/Bystander Exposure and Risk Assessment

The proposed new use on greenhouse ornamentals and greenhouse peppers on the Influence WP label is as a drench application to the substrate surface at seeding. There is a potential for dermal and inhalation exposure to the end-use product during mixing, loading and application. Occupational exposure to Influence WP will be minimal if workers follow label recommendations. Precautions on the label include directions to avoid contact with eyes, skin and clothing, and to avoid breathing dust or spray mists. Personal protective equipment required on the label include long-sleeved shirt, long pants, water-proof gloves, and shoes plus socks. Directions on the label specify that this personal protective equipment is to be worn during

mixing, loading, application, and during clean-up and repair activities. Also, mixers and loaders are required to wear a dust/mist filtering respirator (dust mask) meeting a standard of at least N-95, R-95, P-95 or HE and applicators using a power sprayer must wear a bayonet-style cartridge respirator (for particulates) equipped with at least an N-95, R-95, P-95 or HE filter. In addition, the PMRA recommends "Individuals who are sensitive or allergic to garlic should avoid handling the product."

Significant risk from exposure to Influence WP for the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities is not anticipated, due to the low toxicity of the end-use product and reduced occupational exposure when label directions are followed.

Bystander exposure is expected to be negligible because the product is to be applied in greenhouses by commercial applicators, and the Influence WP label states that unprotected persons should be kept out of the treated areas for the duration of the treatment period.

Post-application exposure is not a concern as the Influence WP label currently restricts entry into the greenhouse until after the spray has dried. In addition the product is applied as a drench to the substrate surface at seeding, therefore, post-application exposure is not expected.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

A comprehensive summary of the fate and behaviour in the environment can be found in PRD2010-11, *Garlic Powder* and PRD2012-22, *Garlic Powder*.

4.2 Environmental Risk Characterization

A comprehensive summary of the environmental risk characterization to terrestrial and aquatic organisms can be found in PRD2010-11 and PRD2012-22.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

5.1.1.1 Suppression of Seed Rot, Pre-Emergence Damping-Off and Root Rot on Greenhouse Peppers and Ornamentals

A total of four greenhouse trials on pepper, zinnia, vinca and celosia as well as ten in vitro studies were submitted in support of the proposed claims.

Influence WP at 20 kg/300 m^2 numerically or statistically improved plant emergence and consistently suppressed root rot symptoms caused by *Pythium ultimum* in the four greenhouse trials, which were conducted under moderate to high disease pressure. Lower levels of protection were achieved with the rate of 10 kg/300 m^2 on sweet green pepper, but improved efficacy would be expected under low to moderate disease pressure. Furthermore, the rates of 10 and 20 kg/300m^2 performed similarly on vinca and zinnia, which is supportive of the proposed rate range. The in vitro trials provided additional evidence of the fungicidal activity of garlic powder on *P. ultimum*, *P. aphanidermatum* and *Rhizoctonia solani* at 10 kg/300 m^2.

Based on these value considerations as well as on the non-conventional status of garlic powder, Influence WP is supported for suppression of seed rot, pre-emergence damping-off and root rot (*Pythium* spp.) on greenhouse pepper and greenhouse ornamentals. The four in vitro trials on *R. solani* are considered sufficient to add this pathogen as a causal agent of seed rot, pre-emergence damping-off and root rot on the proposed crops.

5.2 Economics

No economic analysis was performed for this application.

5.3 Sustainability

5.3.1 Survey of Alternatives

Refer to Appendix I, Table 1 for a summary of the active ingredients currently registered for the uses supported with Influence WP.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

When used as recommended, Influence WP is not expected to interfere with the cultural and sanitation practices intended to prevent disease development in greenhouse crops.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Garlic powder is a non-conventional active ingredient with a multi-site mode of action. Consequently, development of disease resistance to the fungicidal activity of garlic powder is not expected. No reports of possible disease resistance are known at this time.

5.3.4 Contribution to Risk Reduction and Sustainability

Garlic powder represents an alternative to conventional chemistries for the management of soil-borne diseases in greenhouse pepper and greenhouse ornamentals.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, garlic powder was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Garlic powder is not expected to be persistent or bioaccumulative (estimated log K_{ow} = 2.6 for allyl sulfide). Therefore, garlic powder technical does not meet Track 1 criteria and is not considered a Track 1 substance.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade garlic powder and the associated end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.*

[6] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[7] NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

[8] DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The available information for garlic powder is adequate to qualitatively identify the toxicological hazards that may result from human exposure to garlic powder. Garlic powder is of low acute toxicity by oral and dermal routes. It is slightly irritating to skin and eyes, but is a potential skin sensitizer. Repeated dermal exposure to Garlic Powder Technical and Influence WP can result in skin sensitization. Due to the irritative nature of garlic powder, inhalation exposure is likely to cause irritation of the respiratory tract.

Occupational and residential exposure to Influence WP are expected to be minimal if the precautionary statements and required personal protective equipment on the product label, which are intended to minimize worker exposure, are observed. Bystander exposure is likely to be negligible to nonexistent. Postapplication exposure can be minimized by restricted entry.

7.2 Environmental Risk

Garlic Powder Technical is derived from a naturally-occurring food commodity (garlic bulb). Garlic powder and its active components (allyl sulfides) are expected to dissipate rapidly in the environment and degrade through reactions with photochemically produced hydroxyl radicals. The use of Garlic Powder Technical is expected to pose negligible risks to non-target terrestrial and aquatic organisms as environmental exposure will be minimal.

7.3 Value

The value information submitted to register Influence WP is adequate to support the following claims:

- suppression of seed rot, pre-emergence damping-off and root rot (*Pythium* spp., *R. solani*) on greenhouse peppers
- suppression of seed rot, pre-emergence damping-off and root rot (*Pythium* spp., *R. solani*) on greenhouse ornamentals

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Garlic Powder Technical and Influence WP, containing the technical grade active ingredient garlic powder, to suppress of seed rot, pre-emergence damping-off and root rot on greenhouse peppers and greenhouse ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

CAS	Chemical Abstracts Service
cm^3	centimetre(s) cubed
F	fumigant
g	gram(s)
HDPE	high density polyethylene
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
m^2	metre(s) squared
mL	millilitre(s)
N/A	not applicable
NC	not classified
PE	polyethylene
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PP	polypropylene
TSMP	*Toxic Substances Management Policy*
UV	ultraviolet
WP	wettable powder

Appendix I Tables and Figures

Table 1 Summary of Fungicide Alternatives for the Uses Supported with Influence WP

Crop	Pests	Active Ingredient and Resistance Management Group
greenhouse peppers	seed rot, pre-emergence damping-off, root rot (*Pythium* spp., *Rhizoctonia solani*)	- propamocarb hydrochloride (28) - captan (M4) - dazomet (F) - *Gliocladium catenulatum* strain J1446 (NC) - *Trichoderma harzianum* Rifai strain KRL-AG2 (NC)
greenhouse ornamentals	seed rot, pre-emergence damping-off, root rot (*Pythium* spp., *Rhizoctonia solani*)	- thiophanate-methyl (1) - metalaxyl (4) - trifloxystrobin (11) - etridiazole (14) - propamocarb hydrochloride (28) - fosetyl-Al (33) - copper (M1) - captan (M4) - folpet (M4) - dazomet (F) - metam potassium (F) - metam sodium (F) - *Bacillus subtilis* strain MBI 600 - *Bacillus subtilis* strain QST 713 - *Gliocladium catenulatum* strain J1446 (NC) - *Trichoderma harzianum* Rifai strain KRL-AG2 (NC)

Table 2 Use (Label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed claim	Supported / Unsupported
Greenhouse peppers: suppression of damping-off and root rot (*Pythium* sp., *Rhizoctonia* sp.) with one drench application at seeding at 10–20 kg/300 m^2	Supported for suppression of seed rot / pre-emergence damping-off and root rot caused by *Pythium* spp. and *Rhizoctonia solani*.
Greenhouse ornamentals: suppression of damping-off and root rot (*Pythium* sp., *Rhizoctonia* sp.) with one drench application at seeding at 10–20 kg/300 m^2	Supported for suppression of seed rot / pre-emergence damping-off and root rot caused by *Pythium* spp. and *Rhizoctonia solani*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number	Reference
2202611	2012, Use Description, DACO 5.2

2.0 Value

PMRA Document Number	Reference
2202585	2012, Value Summaries, DACO: 10.1
2202593	2012, Summary, DACO: 10.2.3.1
2202594	2011, Essai d'efficacité de Biofongicide pour lutter contre Rhizoctonia in vitro, DACO: 10.2.3.2
2202596	2011, Essai d'efficacité de Biofongicide pour lutter contre Rhizoctonia in vitro, DACO: 10.2.3.2
2202597	2011, Essai d'efficacité de Biofongicide pour lutter contre Rhizoctonia in vitro, DACO: 10.2.3.2
2202598	2011, Essai d'efficacité de Biofongicide pour lutter contre Rhizoctonia in vitro, DACO: 10.2.3.2
2202599	2011, Essai d'efficacité de Biofongicide pour lutter contre Rhizoctonia in vitro, DACO: 10.2.3.2
2202600	2011, Essai d'efficacité de Biofongicide pour lutter contre Rhizoctonia in vitro, DACO: 10.2.3.2
2202601	2011, Essai d'efficacité de Biofongicide pour lutter contre pythium in vitro, DACO: 10.2.3.2
2202602	2011, Essai d'efficacité de Biofongicide pour lutter contre pythium in vitro, DACO: 10.2.3.2
2202603	2011, Essai d'efficacité de Biofongicide pour lutter contre pythium in vitro, DACO: 10.2.3.2
2202604	2011, Essai d'efficacité de Biofongicide pour lutter contre pythium in vitro, DACO: 10.2.3.2
2202605	2012, Trial summary report, DACO: 10.2.3.3
2202606	2012, Rapport de recherche zinnia, DACO: 10.2.3.3
2202607	2012, Rapport de recherche vinca, DACO: 10.2.3.3
2202608	2012, Rapport de recherche celosie, DACO: 10.2.3.3
2202609	2012, Rapport de recherche poivrons, DACO: 10.2.3.3
2202610	2012, Non safety adverse effects, DACO: 10.3.1